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| 10/642,348      | 08/15/2003  | Keith K. Daellenbach | BJT 332B            | 1593             |

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| EXAMINER |
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SCHELL, LAURA C

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| ART UNIT | PAPER NUMBER |
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3767

DATE MAILED: 10/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/642,348

Applicant(s)

DAELLENBACH, KEITH K.

Examiner

Laura C. Schell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13-20, 23 and 26-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13-20, 23 and 26-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 recites the limitation "orifices" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 9 depends from claim 1, which recites "orifice".

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 6, 7 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Hauschild et al. (US Patent No. 6,905,475). Hauschild discloses a needle-free jet injection device (see abstract, lines 5-11) for delivering a fluid into an internal organ, the device comprising: a rigid end effector (Fig. 6, 27; also see col. 4, lines 34-35) having a blunt distal end (Fig. 6 discloses that the end of the effector is blunt, and furthermore, the Oxford online dictionary's definition of "blunt" is: "having a flat or rounded end" which, as Fig. 6 demonstrates, the end(s) of the end-effector is/are rounded. {[http://www.askoxford.com/concise\\_oed/blunt?view=uk](http://www.askoxford.com/concise_oed/blunt?view=uk)}) and including at least one injection orifice (90) disposed on a sidewall of the end effector, the end effector having a longitudinal axis configured into a shape wherein the end effector is sufficiently rigid to maintain the shape of its longitudinal axis during use (col. 4, lines 34-35); the end effector being adapted to be positioned within a prostatic section of a patient's urethra adjacent the patient's prostate gland wherein the at least one injection orifice is oriented generally laterally to the longitudinal axis of the end effector (Fig. 6; col. 5, line 56 through col. 6, line 13); a fluid reservoir (Figs. 9 and 10, 86) in fluid communication with the end effector; and an ejection mechanism (Figs. 9 and 10) adapted to eject the fluid from the fluid reservoir through the end effector and out of the injection orifice with sufficient pressure to penetrate the prostate gland while preserving functionality of the prostate gland (col. 5, line 56 through col. 6, line 13; col. 6, line 35 through col. 7, line 27).

In reference to claim 6, Hauschild discloses that the ejection mechanism is further adapted to allow the device to eject multiple doses of fluid without refilling the

fluid reservoir (Figs. 3 and 4 disclose that a syringe can be used and therefore is capable of providing multiple doses without refilling; also see col. 3, lines 37-41 which disclose that multiple injections can be made to the various lobes of the prostate within the same procedure).

In reference to claim 7, Hauschild discloses that the fluid includes ethanol (see abstract).

In reference to claim 23, Hauschild discloses that the shape of the longitudinal axis of the end effector is generally straight (Figs. 3, 4 and 6).

Claim 18 is rejected under 35 U.S.C. 102(e) as being anticipated by Hauschild et al. (US Patent No. 6,905,475). Hauschild discloses a needle-free jet injection device for delivering a fluid into selected internal tissue (see abstract, lines 5-11), the device comprising: a rigid end effector (Fig. 6, 27; also see col. 4, lines 34-35) having a blunt distal end (Fig. 6 discloses that the end of the effector is blunt, and furthermore, the Oxford online dictionary's definition of "blunt" is: "having a flat or rounded end" which, as Fig. 6 demonstrates, the end(s) of the end-effector is/are rounded.

{[http://www.askoxford.com/concise\\_oed/blunt?view=uk](http://www.askoxford.com/concise_oed/blunt?view=uk)}) and at least one injection orifice (90) disposed on a sidewall of the end effector, the end effector being adapted to be positioned with the injection orifice adjacent the selected internal tissue, the end effector having a longitudinal axis configured to a shape wherein the end effector is sufficiently rigid to maintain the shape of its longitudinal axis during use (col. 4, lines 34-35), wherein the at least one injection orifice is oriented generally laterally to the longitudinal axis of the end effector (Fig. 6, 90); and a fluid reservoir (Figs. 9 and 10, 86)

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in fluid communication with the end effector; and an ejection mechanism adapted to eject the fluid from the fluid reservoir through the end effector and out of the injection orifice with sufficient pressure to penetrate the selected internal tissue while preserving functionality of the tissue, wherein the ejection mechanism may be adjusted to provide an appropriate system pressure for the selected internal tissue (col. 5, line 56 through col. 6, line 13; col. 6, line 35 through col. 7, line 27).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2-5 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauschild et al. (US Patent No. 6,905,475) in view of Paskar (US Patent No. 6,623,449).

In reference to claims 2-5, Hauschild discloses the device substantially as claimed, including a rigid end effector (Fig. 6) and an injection orifice (90) located in the distal section of the straight shaft (Fig. 6), however, Hauschild does not disclose that the end effector includes a plurality of injection orifices. Paskar, however, discloses a jet injection system (Fig. 16) which has a plurality of injection orifices (134) located at the distal section. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Hauschild with the plurality of injection orifices, as taught by Paskar, in order to be able to treat the entire prostate and once for a faster procedure.

In reference to claims 8-10, Hauschild discloses the device substantially as claimed including an injection orifice, however Hauschild does not disclose that the injection orifices are arranged linearly or in multiple offset rows. Paskar, however, discloses a jet injector system (Fig. 16) which includes injection orifices (134) arranged linearly and in multiple offset rows along the length of the end effector. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Hauschild with the plurality of injection orifices and the arrangement of the orifices, as taught by Paskar, in order to provide an end effector that can treat a greater surface area of tissue without missing portions of the tissue to be treated, thus creating a shorter treatment time.

Claims 11 and 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauschild et al. (US Patent No. 6,905,475) in view of Paskar (6,623,449).

Hauschild discloses the device substantially as claimed including: a needle-free jet

injection device for delivering a fluid into an internal organ (see abstract, lines 5-11), the device comprising: a fluid reservoir (Figs. 9 and 10, 86); a longitudinally rigid extension structure (Fig. 6, 27; also see col. 4, lines 34-35) adapted to be inserted within a patient's urethra so that a distal region of the extension structure is positioned adjacent the patient's prostate gland (Fig. 6; col. 5, line 56 through col. 6, line 13), wherein the distal region of the extension has an at least partially hollow interior that fluid communicates with the fluid reservoir (Fig. 6), wherein the extension structure is sufficiently rigid to maintain a longitudinal shape during use (col. 4, lines 34-35), wherein the distal region has a blunt distal end (Fig. 6 discloses that the end of the effector is blunt, and furthermore, the Oxford online dictionary's definition of "blunt" is: "having a flat or rounded end" which, as Fig. 6 demonstrates, the end(s) of the end-effector is/are rounded. {[http://www.askoxford.com/concise\\_oed/blunt?view=uk](http://www.askoxford.com/concise_oed/blunt?view=uk)}); and an ejection mechanism (Figs. 9 and 10) adapted to eject the fluid from the fluid reservoir (86) through the extension structure and out of an injection orifice (Fig. 6, 90) provided in a sidewall of the distal region of the extension structure with sufficient pressure to penetrate the prostate gland while preserving functionality of the prostate gland, wherein the orifice is oriented in a direction generally lateral to a longitudinal axis of the extension structure (Fig. 6, 90). Hauschild, however, does not disclose that the extension structure includes a plurality of orifices. Paskar, however, discloses a jet injection system (Fig. 16) with an end effector (Fig. 131) that has a plurality of jet injection orifices arranged in the side wall of the end effector (134). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have



modified Hauschild with the plurality of orifices, as taught by Paskar, in order to provide an end effector that is capable of treating a larger surface area of the prostate in one treatment, in order to provide a faster treatment.

In reference to claims 13-17, Hauschild discloses the device substantially as claimed, including that the fluid contains ethanol (see abstract). Hauschild, however, does not disclose a plurality of injection orifices arranged in offset rows. Paskar, however, discloses that the injection orifices (134) are arranged linearly in multiple offset rows (Fig. 16) along the length of the end effector, and that they are oriented in a direction generally lateral to a longitudinal axis of the distal region of the extension structure (Fig. 16). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Hauschild with the arrangement of the plurality of orifices, as taught by Paskar, in order to provide an end effector that is capable of treating a larger surface area, without missing portions of the prostate, which would be avoided with the offset rows, in order to provide a more efficient treatment.

Claims 19, 20 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauschild et al. (US Patent No. 6,905,475) in view of Kollias et al. (US Patent No. 6,251,099). Hauschild discloses the device substantially as claimed including an injection mechanism in which the injection pressure can be adjusted and selected (Figs. 9 and 10; col. 6, line 35 through col. 7, line 27), however, Hauschild does not disclose a mechanism configured to provide a rise time to a peak pressure wherein the rise time and peak pressure selection are to preserve tissue functionality. Kollias, however, discloses a needle-less injection device in which the peak injection

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pressures and rise time to these pressures can be selected in order to preserve the functionality of the tissue (col. 1, lines 55-64). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Hauschild with the rise time and peak pressure selection of Kollias, in order to provide a safe and customizable medical device.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-11, 13-20 and 26-28 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LCS

*LCS*

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

*Kevin C. Sirmons*